ORAL RINSE

CROSS REFERENCE TO RELATED APPLICATIONS - Not Applicable

Statement Regarding Federally Sponsored Research or Development – Not

Applicable

Reference to Microfiche Appendix - Not Applicable

BACKGROUND OF THE INVENTION

- 1. This invention is directed to an oral rinse to promote prophylaxis, prevention of oral disease, and natural healing of inflammation sites, and to a method of treating inflammatory disorders of the mouth.
- 2. In the treatment of tongue-piercing inflammation sites within the mouth, use has been made of a soothing formulation containing Water; Vegetable Glycerine; Sea Salt; Peppermint Oil; and Tea Tree Oil.

BRIEF SUMMARY OF THE INVENTION

A new use has been found for a known formulation, previously used in one embodiment as a soothing dressing when applied to a site of tongue piercing.

It has been found that this formulation is beneficial in promoting: healing in periodontal infection; oral bone regeneration; treatment of apthous ulcers, herpes simplex and gingivitis.

Further investigation is proceeding in the use of this formulation in the treatment of herpes, as manifested in mouth sores. Partially completed tests (which are in course of completion), have yielded positive results, which have been submitted for evaluation to a university Periodontal Department. That Department is including in its study the treatment of oral mucocytis using the same formulation.

A second, independent study, involves the treatment of Herpes Simplex, again using the same formulation.

The formulation of a batch consisted of:

water –	66,192 mls;	74.7
vegetable glycerine – 6720mls;		9.8
sea salt –	5040 mls;	12.3
peppermint oil –	2.5 mls; (Mentha arvensis)	1.7
tea tree oil –	2.5 mls. (Melaleuca alterni	folia 1.7

The invention further comprises a method of treating inflammatory disorders of the mouth, including pierce sites, sites of abrasion, periodontal and herpes inflammation sites, aptous ulcers, gingival inflammation, and "denture sore mouth" by the application of the given topical composition.

DETAILED DESCRIPTION OF THE INVENTION

The following characteristics are attributed to the respective components of the formulation:

Water – serves as carrier and solvent;

Vegetable glycerine serves as solvent/dispersant and taste element;

Sea salt – antiseptic;

Peppermint oil – analgesic, antibiotic, antiseptic, anti-inflamatory;

Tea Tree oil - antiseptic, anti-fungal, anti-bacterial, anti-viral, immune system stimulant.

The formulation is prepared by adding the sea salt and vegetable glycerine to the water, in a stainless steel vessel, and stirring with a stainless steel paddle until the sea salt is

dissolved. After passing the water/glycerine/sea salt solution through an ultra violet light field, the solution is then dispensed into amber coloured glass bottles, to minimize the adverse effects of light, to which tea tree oil is susceptible

The peppermint oil and tea tree oil are measured into a separate container, and there mixed. The mixed peppermint/tea tree oils are then accurately dispensed as a metered quantity into each of the respective glass bottles.

The bottles are then sealed and capped with a black phenolic cap having a low density polyethylene cone liner, and safety sealed, and then boxed.

The bottles include a direction to the user to thoroughly shake the bottle before use, in order to effectively mix the dispensed oils with the other constituents.

The formulation has been applied:

in the form of a mouthwash; or

by way of a spray; or by

direct application to affected areas, being painted on by way of a Q-Tip.

Tests and test results

Herpes – herpal infections ranging from symptomatic onset, to sores ranging in diameter from 2-mm to 3-cm were treated with application of the topical formulation 3-4 times daily. Effectively 100% success rate of cure after 2-3 days treatment.

The symptomatic herpes onset is evidenced by tingling at the site, with no developed eruption. Termination of this tingling after due treatment was taken as evidence of a cure.

Aptous ulcers. Treatment as for Herpes (above), with corresponding rate of total success.

Gingival Proliferation (Denture Sore Mouth) due to ill-fitting dentures -characterized by

the proliferation of oral mucosa. Treatment by topical application 3-times daily.

This led to a 100% cure effected over 4-5 days of treatment. No surgery required.

Periodontitis – the presence of periodontal pockets in excess of 3mm (3-mm pockets are considered normal). Treatment with topical application 3-4 times daily; led to 50% bone regeneration: – 7mm periodontal pockets diminished to 5mm after treatment series;

5mm periodontal pockets diminished to 4mm after treatment series;

Microbial Tests

The subject formulation, identified herein as MDM, was applied by way of a spray.
 Microbial strain – Escherichia coli ATCC 25922. Lapsed time after treatment – 1-hour.
 Bacterial Enumeration (CFU per mililitre)

4 mm periodontal pockets diminished to 3mm after treatment series;

Colony 1 colony 2 colony 3 Average 1-hrLog reduct'n Reduction % 5,100,000 6,000,000 4,800,000 5,3000,000 6.7 99.99

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2. The subject formulation, identified herein as MDM, was applied by way of a spray.

Microbial strain – Staphylococcus aureus ATCC 25923. Lapsed time– 1-hour.

Bacterial Enumeration (CFU per mililitre)

Colony 1 colony 2 colony 3 Average 1-hrLog reduct'n Reduction % 4,900,000 4,700,000 4,300,000 4,633,333 6.7 99.99

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3. The subject formulation, identified herein as MDM, was applied by way of a spray.

Microbial strain – Pseudomonas aeruginosa ATCC27853. Lapsed time– 1-hour.

Bacterial Enumeration (CFU per mililitre)

Colony 1 colony 2 colony 3 Average 1-hrLog reduct'n Reduction % 5,100,000 6,000,000 4,800,000 5,3000,000 6.7 99.99

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Those skilled in the art will appreciate that the invention described herein is susceptible to variations and modifications other than those specifically described. It is to be understood that the invention includes all such variations and modifications. The invention also includes all of the steps, features, compositions and compounds referred to or indicated in this specification, individually or collectively, and any and all combinations of any two or more of the aforesaid steps or features.